

Original Research Article

Enhanced recovery after surgery protocol versus conventional care in emergency abdominal trauma surgery: a prospective, randomised, controlled study

Ajay Kumar Dhiman, Nilesh Jagne, Madhur Uniyal*, Ajay Kumar, Quamar Azam

Department of Trauma Surgery, AIIMS Rishikesh, India

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***Correspondence:**

Dr. Madhur Uniyal,

E-mail: ajaydhiman04@gmail.com

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ABSTRACT

Background: Since 1990s there has been a defined role of ERAS in elective surgeries, to optimize the peri-operative care, reducing post-operative complications and length of stay and hence, the overall costs. However, there is paucity of literature in its effectiveness in emergency trauma surgeries. The aim of the study was to investigate the feasibility and outcomes of ERAS protocol in emergency abdominal surgery in the setting of trauma.

Methods: Institutional IEC approved study. A prospective randomized of 52 patients with abdominal trauma undergoing emergency laprotomy were included in the study and divided into two groups: ERP and conventional group. The ERP included early feeding, early urinary catheter removal, early mobilization/physiotherapy, early intravenous line removal and early optimal oral analgesia. The primary end-points were the length of hospital stay and secondary end-points included complication rate and re-admission rate.

Results: The two groups were comparable with regards to age, gender, mechanism of injury and ISS score. Hospital stay was significantly shorter in the ERAS group: 4.67 days versus 13.36 days ($p < 0.001$). There were 15 and 11 complications in the control and study group respectively. When graded as per the Clavien-Dindo classification there was no significant difference in the 2 groups ($p = 0.306$).

Conclusions: This study shows that early recovery programs can be successfully implemented with significant shorter hospital stays without any increase in postoperative complications in trauma patients undergoing emergency laparotomy for abdominal trauma.

Keywords: ERAS, Conventional protocol, Emergency laparotomy, Trauma surgery

INTRODUCTION

Enhanced recovery after surgery (ERAS) is a standardization of care aimed at minimizing surgical stress response, reducing complications, enhancing outcome, reducing hospital stay, and expediting recovery from surgery.¹

Since the 1990s, ERAS is being used as part of elective surgeries, especially colorectal surgeries, to optimize perioperative care, reduce complications after surgery, and reduce length of stay, thus reducing costs.² A small number

of studies have investigated the effectiveness of ERAS for emergency surgery patients, despite the volume of literature on elective surgery ERAS, although some guidelines suggest its appropriate use.³ An emergency surgery is any surgical procedure needed to handle a situation that represents an acute threat to life, organ, limb, or tissue caused by external trauma, acute disease process, acute exacerbation of chronic disease, or complication of a surgical or other interventional procedure. Within 24 hours, emergency surgeons must be able to perform abdominal (including urological), thoracic, vascular, and soft tissue procedures.⁴

As one of the key hospital services, emergency surgery is the largest proportion of surgical patients. Surgery is associated with a high mortality rate as well as high morbidity rates.⁵ So there have been strong recommendations on implementing ERAS in emergency services in order to decrease the peri-operative and post-operative morbidity and mortality.

The majority of emergency trauma surgeries encountered at our place are cases of blunt and penetrating traumatic perforations, which are associated with high risk of morbidity and mortality if left undiagnosed or if diagnosed late.

ERAS have been defined in elective surgery; however, there is very little evidence of their use in emergency surgery.² This is majorly because the guidelines do not completely get fulfilled with respect to emergency surgeries. But nowadays, it has been seen that there has been a substantial role of ERAS in emergency surgeries.¹

In this prospective randomized clinical study, we compared the effect of ERAS protocol versus conventional care protocol on the clinical outcome of the patients undergoing emergency trauma surgeries.

METHODS

Study design and sample size

This was a single centered prospective RCT conducted in department of trauma surgery and critical care in All India Institute of Medical Sciences (AIIMS), Rishikesh over a period of September 2019 to April 2020 after getting ethical clearance from Institutional ethical committee.

Using study by Gonenc et al, the sample size was calculated using length of hospital stay for power analysis (2 ± 2.2 days). The level of significance was set to 5% and power of the test as 80%.⁶ The ratio of sample size in control group and intervention group is kept as 1:1 and the sample size taken was 50; 25 in control group and 25 in intervention group. The patients were randomly divided into two groups using a computer-generated allocation software and allocation concealment was done by 'sealed envelope technique' to prevent prior knowledge of treatment assignment. The numbers were assigned in strict chronological order and the patients were entered in sequence. The patients, randomization allocation personnel and data collection personnel were blinded to the study.

Patient selection

Stable patients presenting with abdominal trauma that required an emergency laparotomy over a were randomized into two groups: group A (ERAS protocol) and group B (conventional care protocol). Following are inclusion and exclusion criteria of the study:

Inclusion criteria

Patients presenting to trauma emergency department, AIIMS, Rishikesh requiring emergency laparotomy and hemodynamically stable/responder were included.

Exclusion criteria

Patients with following criteria were excluded: (a) moderate to severe head injuries; (b) requiring damage control surgery due to intra-operative deterioration/any reason; (c) post-op ventilation; (d) pancreatico-duodenal injuries; and (e) denial of consent.

Peri-operative protocols

Based on ERAS consensus guidelines an ERP was designed. The ERP included: early nasogastric tube removal, early urine catheter removal, early intravenous line removal, early feeding with early fluid and solid diet initiation, early mobilization/physiotherapy, and early optimal oral analgesia. Criteria for early discharge included: tolerance of solid diet, pain control on oral analgesia and independent mobilization.

In our study, the post-operative pain protocol consisted of a morphine infusion for up to 48 hours and paracetamol infusion for 24 hours. Thereafter patients were converted to oral analgesia (paracetamol and tramadol) and intramuscular morphine for breakthrough pain. All patients were mobilized on the first post-operative day with the help of nursing staff and physiotherapists, with the goal of having all patients fully independent by day 3. This approach to post-operative pain control and mobilization was already well established in our unit and all patients in both the control and study group benefited from it. Early mobilization and early optimal oral analgesia were therefore similar for both groups and not significant.

The ERP was implemented and a prospective cohort of 52 patients are divided into two groups: ERP and conventional group. Demographic data, adherence to the ERP, length of hospital stay and postoperative complications as per Clavien-Dindo classification were analyzed.

Outcome measures

These primary end-points was the length of hospital stay and secondary endpoints were post-operative complications rate and re-admission rate.

Statistical analysis

Statistical analysis is performed using SPSS statistical software. Discrete variables are expressed as counts and percentages. The Student t test is used for comparisons between continuous variables. The Mann-Whitney test is

used for other non-parametric quantitative unpaired data. Statistical significance is defined as $p < 0.5$.

RESULTS

The study included 52 patients (27- ERAS and 25- non-ERAS). The 2 groups were comparable with regard to age, gender, mechanism of injury, Injury severity scores (ISS).

The mean time to solid diet, urinary catheter removal and NGT removal was (non-ERAS)- 3.72 and (ERAS)- 2.04 days ($p < 0.001$), (non-ERAS)- 3.17 and (ERAS)- 1.00 days ($p < 0.001$), (non-ERAS)- 2.95 and (ERAS)- 1.00 days ($p < 0.001$), respectively. Patients in the ERAS group had statistically significant earlier removal of nasogastric tubes, urinary catheters and earlier initiation of solid diet (Table 1).

Mean hospital length of stay was 5.5 days (SD-1.8) in the ERAS group and 8.4 days (SD-4.2) in the non-ERAS group (Table 2). The shorter length of hospital stay in the ERAS group was statistically significant, ($p < 0.00021$).

The Clavien-Dindo classification system was used to record post-operative complications (Table 3). There were 15 and 11 complications in the non-ERAS and ERAS group, respectively. When graded as per the Clavien-Dindo classification there was no statistically significant difference in postoperative Complications grade for grade and overall between the non-ERAS group and ERAS group ($p < 0.309$).

There was no significant difference between the various groups in terms of distribution of readmission ($\chi^2 = 0.939$, $p = 0.411$) (Table 4).

Table 1: Association between group and parameters.

Parameters	Group		P value
	Conventional (n=25)	ERAS (n=27)	
Age (years)	30.08±13.72	28.85±12.66	0.739 ¹
Gender			0.284 ²
Male	19 (76.0%)	24 (88.9%)	
Female	6 (24.0%)	3 (11.1%)	
ASA			0.058 ³
IE	9 (36.0%)	9 (33.3%)	
IIE	6 (24.0%)	14 (51.9%)	
IIIE	10 (40.0%)	4 (14.8%)	
IVE	0 (0.0%)	0 (0.0%)	
ISS	19.70±4.99	16.08±6.21	0.051 ⁴
Time since injury (hours)	36.74±50.76	161.04±688.14	0.839 ⁴
Heart rate (BPM)	105.08±17.15	96.74±11.91	0.050 ¹
Systolic BP (mmHg)	114.32±14.34	119.63±15.40	0.204 ¹
Diastolic BP (mmHg)	75.76±10.74	75.93±9.02	0.952 ¹
SpO ₂ (%)	98.08±1.00	98.15±1.03	0.676 ⁴
BMI (kg/m ²)	21.96±2.41	21.20±1.87	0.213 ¹
Hemoglobin (g/dl)***	11.77±2.09	13.18±2.17	0.301 ¹
TLC (per mm ³)	10479.14±6968.51	9487.18±5063.61	0.833 ⁴
Platelet count (Lac)	2.22±0.81	2.08±0.78	0.538 ¹
INR	1.30±0.55	1.29±0.35	0.633 ⁴
Urea (mg/dl)	37.04±37.29	33.96±28.13	0.840 ⁴
Serum creatinine (mg/dl)	1.09±1.26	1.05±0.85	0.327 ⁴
S. sodium (meq/l)	138.28±5.92	137.77±5.68	0.757 ¹
S. potassium (meq/l)	4.11±0.56	4.20±0.52	0.536 ¹
Serum albumin (g/dl)	3.18±0.69	3.43±0.79	0.226 ¹
NPO duration (hours)***	3.88±1.83	2.20±0.65	<0.001 ⁴
Bowel preparation (yes)	1 (4.0%)	2 (7.4%)	1.000 ²
Antibiotics (yes)	25 (100.0%)	27 (100.0%)	1.000 ³
N and V prophylaxis (yes)	25 (100.0%)	27 (100.0%)	1.000 ³
Epidural anesthesia (yes)***	9 (36.0%)	22 (81.5%)	<0.001 ³
CVP (yes)***	10 (40.0%)	20 (74.1%)	0.013 ³
PUC (yes)	25 (100.0%)	27 (100.0%)	1.000 ³
NGT (yes)	21 (84.0%)	20 (74.1%)	0.381 ³
Drain (yes)***	23 (92.0%)	10 (37.0%)	<0.001 ³
OT time (minutes)***	168.00±51.96	150.56±44.09	0.271 ⁴
Blood loss (ml)***	266.00±145.57	261.11±135.54	0.302 ⁴

Continued.

Parameters	Group		P value
	Conventional (n=25)	ERAS (n=27)	
Post-operative analgesia (yes)	25 (100.0%)	27 (100.0%)	1.000 ³
Post-operative blood transfusion (yes)	9 (36.0%)	5 (18.5%)	0.156 ³
Day NGT removal***	2.95±1.72	1.00±0.00	<0.001 ⁴
Day of PUC removal***	3.17±2.48	1.00±0.00	<0.001 ⁴
Day of drain removal***	4.22±2.24	2.00±0.00	0.001 ⁴
Day of liquid diet initiation***	1.64±1.85	0.19±0.40	<0.001 ⁴
Day of soft diet initiation***	2.80±1.98	1.11±0.32	<0.001 ⁴
Day of normal diet initiation***	3.72±2.09	2.04±0.52	<0.001 ⁴
Day of ambulation***	2.14±1.98	0.96±0.35	<0.001 ⁴
Day of flatus passage***	2.08±1.04	1.48±0.58	0.020 ⁴
Day of feces passage***	2.88±1.09	2.19±0.56	0.007 ⁴
Post-operative pain score***	4.48±1.26	3.48±0.58	0.001 ⁴
Duration of hospital stay (days)***	13.36±10.84	4.67±1.75	0.001 ⁴
Bleeding (yes)	0 (0.0%)	0 (0.0%)	1.000 ³
Ileus (yes)***	9 (36.0%)	2 (7.4%)	0.012 ³
Vomiting (yes)	6 (24.0%)	2 (7.4%)	0.134 ²
Urinary retention (yes)	0 (0.0%)	0 (0.0%)	1.000 ³
Chest infection (yes)	5 (20.0%)	2 (7.4%)	0.241 ²
SSI (yes)	8 (32.0%)	4 (14.8%)	0.142 ³
DVT (yes)	0 (0.0%)	0 (0.0%)	1.000 ³
NG reinsertion (yes)	7 (28.0%)	2 (7.4%)	0.071 ²

Note: ***Significant at p<0.05, 1: t-test, 2: Fisher's exact test, 3: Chi-squared test, 4: Wilcoxon-Mann-Whitney U test.

Table 2: Comparison of the 2 subgroups of the variable group in terms of duration of hospital stay (days).

Duration of hospital stay (days)	Groups		Wilcoxon-Mann-Whitney U test	
	Conventional	ERAS	W	P value
Mean (SD)	13.36 (10.84)	4.67 (1.75)		
Median (IQR)	11 (7-14)	4 (3.5-6)	600.000	<0.001
Range	4 - 40	2 - 10		

Table 3: Association between group and Clavein-Dindo classification.

Clavein-Dindo classification	Groups						Fisher's exact test	
	Conventional		ERAS		Total		χ^2	P value
	N	%	N	%	N	%		
Grade 1	4	26.7	3	27.3	7	26.9	6.458	0.306
Grade 2	4	26.7	5	45.5	9	34.6		
Grade 3a	0	0.0	2	18.2	2	7.7		
Grade 3b	5	33.3	1	9.1	6	23.1		
Grade 4b	1	6.7	0	0.0	1	3.8		
Grade 5	1	6.7	0	0.0	1	3.8		
Total	15	100.0	11	100.0	26	100.0		

Table 4: Association between group and readmission (N=52).

Readmission	Groups						Fisher's exact test	
	Conventional		ERAS		Total		χ^2	P value
	N	%	N	%	N	%		
Yes	4	16.0	2	7.4	6	11.5	0.939	0.411
No	21	84.0	25	92.6	46	88.5		
Total	25	100.0	27	100.0	52	100.0		

DISCUSSION

ERAS programs have consistently been shown to have both cost-related and patient-related benefits. King et al. examined the influence of an ERP on clinical outcome, cost and quality of life after surgery for colorectal surgery.⁷ They found that hospital stay was significantly reduced when patients were managed according to an ERP, with a 49% reduction in length of stay in the ERP group compared to the conventional care arm. They also showed no transfer of costs onto another health care industry.

In a meta-analysis of randomized controlled trials evaluating health outcomes and resource utilization, patients adhering to the ERP had reduced length of stay of 2.5 days, and this was a reproducible improvement in the quality of care by enabling standardization of health care processes.⁸ Similarly, our study confirms this concept with a 44% reduction in hospital stay. Duration of hospital stay and peri-operative morbidity and complication rate are key determinants of cost. On reviewing the initial studies, we found a case matched study by Lohsiriwat et al published in 2014 which included 60 patients divided into ERAS and non-ERAS groups in the ratio of 1:2 undergoing emergency resection for obstructive colorectal cancer.⁹ He concluded a significantly shorter length of hospital stay along with no difference in 30 days mortality and re-admission rates which was similar to our study. A randomized control trial performed by Gonenc et al in 2014 analysed the feasibility of ERAS protocols in emergency laparoscopic surgery for perforated peptic ulcer and concluded similar results as our study.⁶ It also negated the use of nasogastric tube for decompression and delayed oral feeding which was in itself a landmark.

Wisely et al, in 2016, published a retrospective cohort study comparing 370 patients undergoing emergency abdominal surgeries for various diseases before and after the introduction of ERAS protocols and concluded that patients in ERAS group had significantly fewer patients who required catheters, drains or post-operative analgesia for more than 2 days. Major post-operative complications like urinary tract infections, chest infections and urinary retention were significantly reduced as was concluded by our study. However, in contrary to our study, Wisely et al concluded similar duration of hospital stay in both ERAS and non-ERAS groups.¹⁰ Another study by Shida et al in 2017 evaluated 122 patients undergoing bowel resections for obstructive colon cancer at a general hospital in Tokyo which concluded that ERAS protocols resulted in reduced median hospital stay by 3 days and a comparable rate of re-admission and mortality as concluded by our study, but in contrast, also reported no significant reduction in post-operative complication rates.¹¹

Abdominal surgery is associated with postoperative pain, paralytic Ileus, reduced pulmonary function and loss of muscle mass and function, all of which may contribute to postoperative morbidity and need for prolonged hospital stay. ERPs aim to reduce these postoperative

complications by preserving the normal preoperative physiology. Thus, by improving patient outcome with early discharge and reduced morbidity we are able to reduce the cost of treating this group of patients. The presence of trans-urethral catheters increases incidence of urinary tract infection and hinder patient mobilization. Urine catheters were consistently removed earlier in the ERAS arm of our study after 1.00 days compared to 3.17 days in the traditionally treated arm. There were no urinary tract infections observed in our group of patients, and all patients achieved early independent mobilization after removal of urinary Catheter. Preservation of body composition is vital in order to reduce post-operative morbidity. Early oral nutrition with protein drinks will preserve lean body mass and maintain work performance. All our patients were started on soft diet on post-operative day 1, and then stepped up to full ward diet by day 2 to 3. In the ERAS arm of our study patients were initiated on solid diet by 1.1 days compared to 2.80 days in the traditionally treated arm, showing earlier initiation of solid diet if patients are managed as per the ERP.

Another factor shown to hinder initiation of oral intake is the presence of a nasogastric tube. As per our ERP, nasogastric tubes were consistently removed early. In the ERAS arm of our study, nasogastric tubes were removed after 1.0 days compared to 2.95 days in the traditionally treated arm. This earlier removal of nasogastric tubes facilitated earlier initiation of oral intake. Early removal of nasogastric tubes, early initiation of liquid diet and early ambulation is associated with earlier return of bowel function and earlier discharge from hospital. In our study, 2 patients in the ERAS arm and 9 patients in the traditionally treated arm developed post-operative ileus. We were able to demonstrate early removal of nasogastric tubes with early initiation of oral nutrition and early mobilization. Early optimal analgesia and early mobilization with physiotherapy are means of improving pulmonary function. Our patients received dedicated chest physiotherapy and were given and taught how to perform chest physiotherapy which has been shown to reduce pulmonary atelectasis. However, 5 patients developed nosocomial pneumonia requiring antibiotics. This was diagnosed by the increased oxygen requirements, pulmonary crepitations, radiological changes on chest radiograph, and elevated white cell counts. Implementation of ERAS programs are feasible as long as they are safe. The shortened length of hospital stay is of no benefit if it leads to increase incidence of post-operative complications. There were 11 complications in the ERAS arm and 15 in the traditionally treated arm. However, when analyzed there was no statistically significant difference between the 2 groups. This showed that the benefit of reduced length of hospital stay can be achieved without any increase in incidence of post-operative complications.

Limitations of this study was inclusion of hemodynamically stable patients, thus having a more favorable outcome than their unstable counterparts. Secondly, surgeries were not performed by single surgeon

and the varied surgical technique may have an impact on the incidence of post-operative complications and clinical outcome of the patients. Goal based intravenous fluid administration was not included in our study.

CONCLUSION

Results of this study demonstrate the safety, effectiveness and feasibility of ERAS protocols in Emergency trauma surgery and conclude that its application can lead to a reduced length of hospital stay with similar rates of post-operative complications mortality and 30 days readmission rate. However, validation of any study requires a repeated measurement of the endpoints which yield consistent values and there is still a large void to fill as not a lot of high quality RCTs or meta-analyses have been done in this aspect and there have been a lot of disparities regarding its effectiveness in the recent times. This study shows that early recovery programs can be successfully implemented with significant shorter hospital stays without any increase in postoperative complications in trauma patients undergoing emergency laprotomy for abdominal trauma. Given the fact that abdominal trauma remains a substantial burden of disease, especially in developing countries such as India, this proven approach to patient care in elective surgery can now be safely employed in the trauma and emergency setting.

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